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L2: Entry 1 of 3

File: USPT

Mar 4, 2003

DOCUMENT-IDENTIFIER: US 6527979 B2

** See image for Certificate of Correction **

TITLE: Catheter systems and methods for their use in the treatment of calcified vascular occlusions

Detailed Description Text (39):

Where the acidic dissolution fluid is dynamically introduced into the vascular site, the dissolution fluid is introduced in a manner such that the flow rate of the dissolution solution through the vascular site of the lesion is generally at least about 10 cc/min, usually at least about 20 cc/min and more usually at least about 60 cc/min, where the flow rate may be as great as 120 cc/min or greater, but usually does not exceed about 1000 cc/minute and more usually does not exceed about 500 cc/minute, where by "volume" is meant the local environment of the occlusion, as defined above. The total amount of dissolution fluid that is passed through the local environment of the lesion during the treatment period typically ranges from about 100 to 1000 cc, usually from about 200 to 800 cc and more usually from about 400 to 500 cc. The solution is generally pressurized to achieve the desired flow rate, as described supra. As such, the pressure at the distal end of the coaxial catheter assembly through which the solution is introduced into the local environment typically ranges from about 50 to 1200 psi, usually from about 100 to 600 psi and more usually from about 200 to 400 psi. It is important to note that the overall pressure in the local environment is maintained at substantially isometric or isobaric conditions. As such, the negative pressure at the entrance to the aspiration catheter, e.g. the open annulus at the distal end of the aspiration catheter will be of sufficient magnitude to provide for substantially isobaric conditions. Preferably, the overall pressure in the local environment is maintained at a value ranging from about 0.1 to 3 psi, usually from about 0.5 to 2.5 psi and more usually from about 1 to 2 psi.

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L2: Entry 2 of 3

File: USPT

Sep 18, 2001

DOCUMENT-IDENTIFIER: US 6290689 B1

TITLE: Catheter devices and methods for their use in the treatment of calcified vascular occlusions

Detailed Description Text (47):

Where the acidic dissolution fluid is dynamically introduced into the vascular site, the dissolution fluid is introduced in a manner such that the flow rate of the dissolution solution through the vascular site of the lesion is generally at least about 10 cc/min, usually at least about 20 cc/min and more usually at least about 60 cc/min, where the flow rate may be as great as 120 cc/min or greater, but usually does not exceed about 1000 cc/minute and more usually does not exceed about 500 cc/minute, where by "volume" is meant the local environment of the occlusion, as defined above. The total amount of dissolution fluid that is passed through the local environment of the lesion during the treatment period typically ranges from about 100 to 1000 cc, usually from about 200 to 800 cc and more usually from about 400 to 500 cc. The solution is generally pressurized to achieve the desired flow rate, as described supra. As such, the pressure at the distal end of the coaxial catheter assembly through which the solution is introduced into the local environment typically ranges from about 50 to 1200 psi, usually from about 100 to 600 psi and more usually from about 200 to 400 psi. It is important to note that the overall pressure in the local environment is maintained at substantially isometric or isobaric conditions. As such, the negative pressure at the entrance to the aspiration catheter, e.g. the open annulus at the distal end of the <u>aspiration catheter</u> will be of sufficient magnitude to provide for substantially isobaric conditions. Preferably, the overall pressure in the local environment is maintained at a value ranging from about 0.1 to 3 psi, usually from a bout 0.5 to 2.5 psi and more usually from about 1 to 2 psi.